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(54) **CRANIOTOMY DRAPE**

KRANIOTOMIE ABDECKTUCH

DRAP POUR CHAMP OPERATOIRE DE CRANIOTOMIE

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D scription

Field of the Inv ntion

[0001] The present invention is in the field of surgical drapes, more particularly in the field of craniotomy drapes.

Background of the Invention

[0002] Draping procedures create an area of asepsis called a sterile field. All sterile items that come into contact with the prepared area about the wound must be restricted within a defined area of safety to prevent transportation of microorganisms into the open wound. The sterile field is created by placement of sterile sheets and towels, or other draping materials, in a specific position to maintain the sterility of surfaces on which sterile instruments and gloved hands may be placed. The patient and operating room table are covered with sterile drapes in a manner which exposes the prepared site of incision and isolates the area of the surgical wound. Objects draped often include instrument tables, basin and Mayo stands, trays, and some surgical equipment.

[0003] Draping materials are selected to create and maintain an effective barrier that minimizes the passage of microorganisms between non-sterile and sterile areas. To be effective, a barrier material should be resistant to blood, aqueous fluid, and abrasion, as lint-free as possible, and drapable. It should maintain an isothermic environment that is appropriate to body temperature. It should meet or exceed the requirements of the current National Fire Protection Standards, so no risk from a static charge exists. Alexander's Care of the Patient in Surgery, eds. M.H. Meeker, R.N., et al., 10th edition (Mosby St. Louis, MO 1995).

[0004] Drapes covering a surface are only considered to be sterile on the side of the drape away from the surface. The portions of the drape hanging down and away from the draped object or person are not considered sterile, since the range of human vision cannot always be counted on to notice breaks in technique and resulting contamination of the drape. p. 117, G.D. LeMaitre, M.D., et al., The Patient in Surgery: A Guide for Nurses, 3rd edition (W.B. Saunders Co. Philadelphia 1975).

[0005] Neurosurgical tables currently in use are normally located over and slightly above the person on whom the operation is to be performed. The table is usually prepared for the surgical procedure by the placement of one or more drapes, each for a specific purpose, in order to cover the non-sterile table and areas surrounding the head of the patient.

[0006] The anesthesiologist in a neurosurgical operation is usually seated to one side or the other of the operating table. It is desirable for the anesthesiologist to observe the face of the patient and the breathing apparatus connected to the patient to properly assess the patient's condition throughout the surgical procedure. Currently, in order to observe the face of the patient, the anesthesiologist eith r lifts up a comer *of* the drape, or attaches the drape to an intravenous bottle standpol , so that the face of the patient may be continuously observed. Obviously this presents problems of contamination, as the sterile field is compromised. Furthermore, neurosurgical operations are very long procedures, in which surgeons sit down for portions of time in wheeled chairs, or move about the head area of the patient. Current drapes trail onto the floor, creating accident hazards for operating room personnel as they walk about the table, as well compromising the sterility of the drape.

[0007] Electric cords and suction lines running along the patient to the head area are usually clamped or tied to the edges of the outer sheet on the table. These cords or lines can become tangled, and when pulled may cause devices to fall to the floor and become unsterile. This represents a risk to the patient while under a general anesthesia for the period of time required for the preparation of new sterile devices. Furthermore, the clamps and ties are usually not versatile or strong enough to allow easy addition or removal of tubes and electrical lines. This results in delay in surgery while operating room personnel undo and re-affix clamps.

[0008] US-A-4,890,628 relates to a surgical drape comprising a main sheet with a fenestration therein and a fluid collection bag attached to the main sheet, for channelling and collecting fluids emanating at the surgical site during an operation.

[0009] Therefore, it is an object of the present invention to provide a drape where the face of the patient may be observed directly by the anesthesiologist without compromising the sterile field.

[0010] It is another object of the invention to provide a drape which does not trail on the floor of the operating room.

[0011] It is a further object of the invention to provide clamps on a drape which are strong and easily adjusted.

Summary of the Invention

[0012] The present invention is a fenestrated craniotomy drape including a main sheet, translucent anesthesia side screens, a gusset forming the corners of the anterior edges of the drape, a run-off collection pouch whose back side is pressed flat and affixed to the drape, with a back side fenestration surrounding the fenestration of the main sheet, and a front side fenestration, and adjustable tube holders. The drape optionally includes a layer of a fenestrated absorbent material between the drape and the pouch, a solids screen and drain port in the pouch, and a ductile material about the edges of the front side fenestration of the pouch that holds the pouch open. The back-side fenestration of the pouch and those of the drape and the absorbent material are covered by an incise sheet, located between the back side of the pouch and the drape. The adhesive side of the incise sheet facing the patient is covered by a releasable back-

ing.

Bri f Description of th Drawings

[0013]

Figure 1 is a perspective view of the craniotomy drape in use.
Figure 2 is an exploded cut-away view of the craniotomy drape in use.
Figure 3 a top view of the craniotomy drape.
Figure 4 is a view of the gusset and the translucent anesthesia screen.
Figure 5 is a view of the adjustable tube holders.
Figure 6 is a perspective view of an overhead table and an operating room table with a patient lying on it.

Detailed Description of the Invention

[0014] The present invention is a fenestrated craniotomy drape including a main sheet, translucent anesthesia side screens, a gusset forming the comers of the anterior edges of the drape, a run-off collection pouch whose back side is pressed flat and affixed to the drape, with a back side fenestration surrounding the fenestration of the main sheet, and a front side fenestration, and adjustable tube holders. The drape optionally includes a layer of a fenestrated absorbent material between the drape and the pouch, a solids screen and drain port in the pouch, and a ductile material about the edges of the front side fenestration of the pouch that holds the pouch open. The back-side fenestration of the pouch and those of the drape and the absorbent material are covered by an incise sheet, located between the back side of the pouch and the drape. The adhesive side of the incise sheet facing the patient is covered by a releasable backing.

General Description

[0015] The craniotomy drape of the current invention, is generally used as illustrated by 110 in **Figure 1**. It is draped over a surgical overhead table 15, under which lies a patient 5 undergoing a craniotomy procedure. The drape is designed to collect solids and fluids, such as body fluids and irrigation fluids, that collect during the course of the procedure.

[0016] **Figure 2** is an exploded cut-away view of the drape 110. The drape includes a fenestrated main sheet 25, on top of which is an optional fenestrated absorbent sheet 30, and on top of that is secured the flat back side of a fenestrated run-off pouch 45, the fenestration, or hole 90 in the back of which is coincident with the fenestration 85 in the absorbent material and the fenestration 20 in the main sheet 25. An incise sheet 65 is layered between the absorbent sheet 30 and the run-off pouch 45, with a releasable backing 70.

[0017] The main sheet 25 may be made from a woven, reusable fabric, but preferably is made from a nonwoven, disposable fabric such as EVOLUTION 3® fabric polypropylene SMS. The EVOLUTION fabric is a three-layer laminate of spunbond, meltblown, and spunbond layers (SMS). An *example* of a suitable fabric is found in U.S. patent no. 4,041,203, entitled, "Nonwoven thermoplastic fabric," listing inventors R.J. Brock and G. H. Meitner. Referring to **Figure 2**, the main sheet 25 should be large enough to cover the patient's body 5. In one embodiment of the invention, the main sheet is approximately 3,4 m (134 inches) long by 1.88 m (74 inches) wide. The main sheet 25 includes a fenestration 20, positioned toward the anterior portion of the drape. In one embodiment, the fenestration is oval, and placed in the midline about 0.61 m (24 inches) from the anterior end of the drape, over the patient's head. The surgical procedure is performed within the fenestration.

[0018] On the top side of the main sheet 25 is optionally layered a fenestrated absorbent sheet 30. The fenestration 85 of the absorbent sheet is coincident with or larger than the fenestration 20 of the main sheet 25. In one embodiment, the absorbent sheet is composed of the material claimed in U.S. patent no. 5,540,979, to inventors Yahiaoui, A., Potts, D.C., Perkins, C.A., Powers, M.D., and Jascomb, J.T., entitled "Porous non-woven bovine blood-oxalate absorbent structure." In one embodiment, the absorbent sheet is approximately 0.91 m (36 inches) long by 0.61 m (24 inches) wide. In one embodiment, the absorbent sheet 30 is affixed to the main sheet 25 using cold glue.

Tube Holders

[0019] One or more adjustable tube holders 75 are secured either to the main sheet 25 or to the absorbent sheet 30 attached to the main sheet. These tube holders, as shown in Figure 5, are made up of two rectangular pieces of a flexible material joined at a center line like the wings of a bi-plane. In one embodiment of the invention, the material is CONTROL-PLUS™ manufactured by the Kimberly-Clark Corporation, located in Neenah, Wisconsin. CONTROL-PLUS™ is polypropylene spunbond/polypropylene meltblown/polyethylene film laminate. The upper piece has a loop and hook fastener arrangement 80 on its outer edges, while the lower piece is secured either to the main sheet 25 of the drape or to the absorbent sheet 30. In one embodiment, the tube holders 75 are affixed using a hot melt. In one embodiment of the invention, the hook and loop fastener is a VELCRO® fastener. In one embodiment of the invention, the upper and lower rectangular pieces are 5.08 cm x 10.16 cm (two inches by four inches), the velcro hook piece is 2.54 cm x 2.54 cm (one inch by one inch), and the velcro loop is 2.54 cm x 5.08 cm (one inch by two inches).

Run-off Pouch

[0020] Secured to the absorbent sheet 30, or to the main sheet 25, is a fenestrated run-off pouch 45 to collect fluids and solids generated during surgery (See **Figur 2** and **Figur 3**). The run-off pouch 45 is preferably made from a fluid-impervious material, such as translucent polypropylene, and optionally includes a drain port 55, to which a suction apparatus may be attached, and a solids screen 50, so that solids will not block the drain port 55. The back side of the run-off pouch 45 is secured to the optional absorbent sheet or directly to the main sheet 25, and includes a fenestration 90 which is roughly coincident with the fenestrations of the main sheet and the optional absorbent sheet. The back side of the run-off pouch 45 surrounds the fenestration 90 on the back side of the pouch. When in use, the closed end of the pouch hangs down and away from the head of the patient 5.

[0021] The fenestration 100 on the front side of the run-off pouch 45 has a ductile material 60 around its borders. The ductile material 60 helps keep the pouch open. In one embodiment of the invention, the ductile material is two parallel metal wires about 0.5 centimeter apart housed in flat plastic, where the plastic is secured to the border of the fenestration 100.

Incise Sheet

[0022] Turning now to **Figure 2**, layered flat between the back side of the run-off pouch 45 and the main sheet 25, or between the optional absorbent sheet 30 and the main sheet 25, is an incise sheet 65, with the adhesive side facing the patient 5. In one embodiment, the incise sheet 65 is a low-density polyethylene film with adhesive on one side. More preferably, the incise sheet 65 is constructed of polyethylene film made by Bertek Inc., St. Albans, VT 05478. The adhesive side is covered with a releasable backing 70. After the releasable backing 70 is removed, the incise sheet 65 is exposed through the main sheet fenestration 20, and will contact the patient 5 when the drape 110 is placed on the patient 5.

Gussets

[0023] As shown in **Figure 1**, and more particularly in Figure 3, on each side of the anterior portion of the main sheet 25 are located gussets 35. These may be of the same material as the main sheet 25. The gussets 35 may be made from a woven, reusable fabric, but preferably are made from a non-woven, disposable fabric such as EVOLUTION 3 ® fabric polypropylene SMS. In one embodiment, the gussets are approximately square, and 0.61 m x 0.61 m (24 inches by 24 inches). The gussets have a main fold line 95 going diagonally across the gussets 35, which, when the drape is in use, prevent the comers of the drape 110 from trailing on the floor. (See **Figur 4**). As shown in **Figure 1**, the gusset causes the comers of the anterior of the drape 110 to become recessed, which also keeps the comer out of the way of surgical personnel in the operating room. In one embodiment, the fold lines 95 are at approximately a 45 degree angle to the front anterior edge of the drape 110.

Translucent Anesthesia Screens

[0024] As shown in **Figure 1**, and more particularly in **Figure 3**, attached to one or more edges of the anterior portion of the main sheet 25 are one or more translucent anesthesia side screens 40. In one embodiment of the invention, they are approximately rectangular, with dimensions of 0.76 m x 1.42 m (30 inches by 56 inches). Preferably, the screens are clear. These side screens may be made of any appropriate translucent plastic, such as clear polyethylene film. These permit the anesthesiologist to view the face of the patient without lifting the drape and compromising the sterile field.

Use of the Drape

[0025] The craniotomy drape 110 is taken out of a pack (not shown) and draped over an overhead table 15 (see **Figure 1** and **Figure 6**), and over a patient 5 lying on the underlying operating table 10. The releasable backing 70 is peeled away, and the adhesive side of the incise sheet 65 is placed on the area of the patient's head prepared for surgery. The run-off pouch 45 hangs down and away from the head of the patient 5. A suction apparatus (not shown) may be connected to the drain port 55, and various electrical wires and tubes may be secured with the tube holders 75. Surgery is performed directly through the incise sheet 65.

Claims

1. A craniotomy drape (110) comprising a main sheet (25), **characterized in that** at least one translucent anesthesia screen (40) is attached to the lateral anterior edges of the main sheet (25).

2. The craniotomy drape (110) of Claim 1 further comprising a fenestration (20) in the main sheet (25).

3. The craniotomy drape (110) of Claim 1 or 2 further comprising an absorbent sheet (30) layered on top of the main sheet (25) which includes a fenestration (85) incident to the fenestration (20) of the main sheet (25).

4. The craniotomy drape (110) of one of the preceeding claims further comprising an incise sheet (65) on top of the main sheet, and a releasable layer (70) on the adhesive sid of the incise sheet (65).

5. The craniotomy drape (110) of one of the preceeding claims further comprising a fenestrated run-off pouch (45) affixed to main sheet (25) or the absorbent sheet (30), with a back side fenestration (90) surrounding the fenestration of the drape, and a front side fenestration (100).

6. The craniotomy drape (110) of Claim 5 wherein the pouch (45) includes a drain port (55), a solids screen (50), and a ductile material (60) near the edge of the front side fenestration (100).

7. The craniotomy drape (110) of Claim 6 wherein the ductile material is metal wire.

8. The craniotomy drape (110) of one of the preceeding claims further comprising one or more tube holders (75) attached either directly to the main sheet (25) or to the absorbent sheet (30).

9. The craniotomy drape (110) of Claim 8 wherein the tube holders (75) are made up of two rectangular pieces of a flexible material joined at a center line, where the upper piece has a loop and hook fastener arrangement (80) on its outer edges, while the lower piece is secured either directly to the main sheet (25) or to the absorbent sheet (30).

10. The craniotomy drape (110) of one of the preceeding claims wherein the anaesthesia screen (40) is clear.

11. The craniotomy drape (110) of one of the preceeding claims, further comprising at least one gusset (35) attached to the lateral anterior edges of the main sheet (25).

Patentansprüche

1. Kraniotomieabdeckung (110) umfassend eine Hauptlage (25), **dadurch gekennzeichnet, dass** wenigstens eine lichtdurchlässige Anästhesieabschirmung (40) an den lateralen vorderen Kanten der Hauptlage (25) angebracht ist.

2. Kraniotomieabdeckung (110) gemäß Anspruch 1, ferner umfassend eine Fensterung (20) in der Hauptlage (25).

3. Kraniotomieabdeckung (110) gemäß Anspruch 1 oder 2, ferner umfassend eine oben auf der Hauptlage (25) angeordnete absorbierende Lage (30), welche eine mit der Fensterung (20) der Hauptlage (25) inzidente Fensterung (85) umfasst.

4. Kraniotomieabdeckung (110) gemäß einem der vorhergehenden Ansprüche, ferner umfassend eine Inzisionslage (65) oben auf der Hauptlage, und eine entfernbare Schicht (70) auf der haftenden Seite der Inzisionslage (65).

5. Kraniotomieabdeckung (110) gemäß einem der vorhergehenden Ansprüche, ferner umfassend eine gefensterte Ablauftasche (45), die an der Hauptlage (25) oder der absorbierenden Lage (30) befestigt ist, mit einer Fensterung (90) auf der Hinterseite, welche die Fensterung der Abdeckung umgibt, und einer Fensterung (100) auf der Vorderseite.

6. Kraniotomieabdeckung (110) gemäß Anspruch 5, wobei die Tasche (45) eine Ablauföffnung (55), ein Feststoffrückhalteelement (50) und ein duktiles Material (60) nahe der Kante der Fensterung auf der Vorderseite (100) umfasst.

7. Kraniotomieabdeckung (110) gemäß Anspruch 6, wobei das duktile Material ein Metalldraht ist.

8. Kraniotomieabdeckung (110) gemäß einem der vorhergehenden Ansprüche, ferner umfassend einen oder mehrere Schlauchhalter (75), welche entweder direkt an der Hauptlage (25) oder an der absorbierenden Lage (30) angebracht sind.

9. Kraniotomieabdeckung (110) gemäß Anspruch 8, wobei die Schlauchhalter (75) aus zwei rechteckigen Teilen eines flexiblen Materials bestehen, welche an einer Mittellinie verbunden sind, wobei das obere Teil eine Haken- und Schlaufenbefestigungsanordnung (80) an seinen äußeren Kanten hat, und wobei das untere Teil entweder direkt an der Hauptlage (25) oder an der absorbierenden Lage (30) gehaltert ist.

10. Kraniotomieabdeckung (110) gemäß einem der vorhergehenden Ansprüche, wobei die Anästhesieabschirmung (40) klar ist.

11. Kraniotomieabdeckung (110) gemäß einem der vorhergehenden Ansprüche, ferner umfassend wenigstens ein Winkelstück (35), welche an den lateralen vorderen Kanten der Hauptlage (25) angebracht ist.

Revendications

1. Champ opératoire pour craniotomie (110) comprenant une feuille principale (25), **caractérisé en ce que** au moins un écran d'anesthésie translucide (40) est fixé aux bords antérieurs latéraux de la feuille principale (25).

2. Champ opératoire pour craniotomie (110) selon la revendication 1, comprenant en outre une fenêtre

(20) dans la feuille principale (25).

3. Champ opératoire pour craniotomie (110) selon la revendication 1 ou 2, comprenant en outre, une feuille absorbante (30) stratifiée sur la feuille principale (25) et qui inclut une fenêtre (85) coïncidant avec la fenêtre (20) de la feuille principale (25).

4. Champ opératoire pour craniotomie (110) selon l'une des revendications précédentes, comprenant en outre, sur la feuille principale, une feuille incrustée (65), et une couche détachable (70) sur la face adhésive de la feuille incrustée (65).

5. Champ opératoire pour craniotomie (110) selon l'une des revendications précédentes, comprenant en outre une poche d'écoulement fenêtrée (45) fixée à la feuille principale (25) ou à la feuille absorbante (30), avec une fenêtre de face arrière (90) entourant la fenêtre de la feuille, et une fenêtre de face avant (100).

6. Champ opératoire pour craniotomie (110) selon la revendication 5, dans lequel la poche (45) inclut un orifice de vidange (55), un tamis (50) pour matières solides, et un matériau malléable (60) près du bord de la fenêtre de face avant (100).

7. Champ opératoire pour craniotomie (110) selon la revendication 6, dans lequel le matériau malléable est un fil de métal.

8. Champ opératoire pour craniotomie (110) selon l'une des revendications précédentes, comprenant en outre un ou plusieurs supports de tube (75) fixés soit directement à la feuille principale (25) soit à la feuille absorbante (30).

9. Champ opératoire pour craniotomie (110) selon la revendication 8, dans lequel les supports de tube (75) sont faits de deux pièces rectangulaires d'un matériau flexible jointes au niveau d'une ligne centrale, où la pièce supérieure a un aménagement de fermeture à bouclettes et crochets (80) sur ses bords extérieurs, tandis que la pièce inférieure est fixée soit directement à la feuille principale (25) soit à la feuille absorbante (30).

10. Champ opératoire pour craniotomie (110) selon l'une des revendications précédentes, dans lequel l'écran d'anesthésie (40) est limpide.

11. Champ opératoire pour craniotomie (110) selon l'une des revendications précédentes, comprenant en outre au moins un soufflet (35) fixé aux bords antérieurs latéraux de la feuille principale (25).

FIG. 1

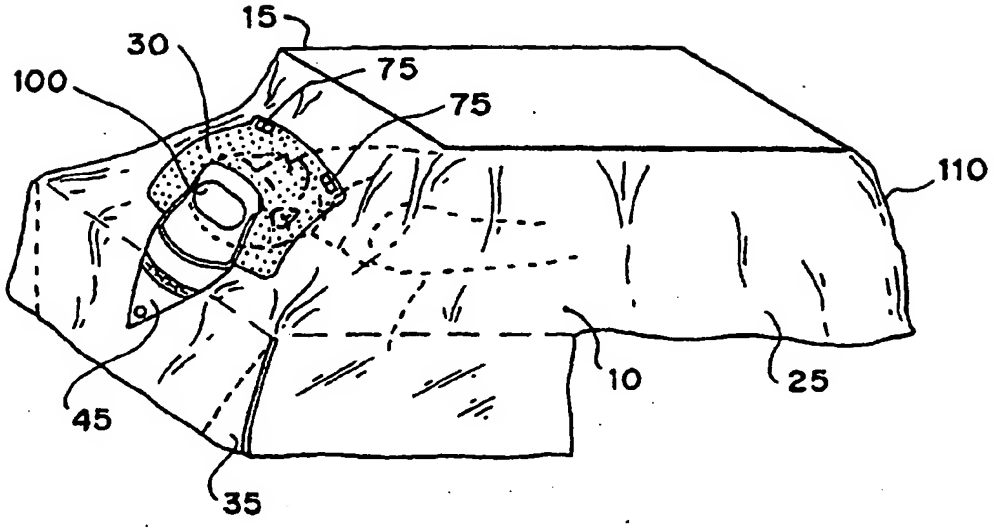
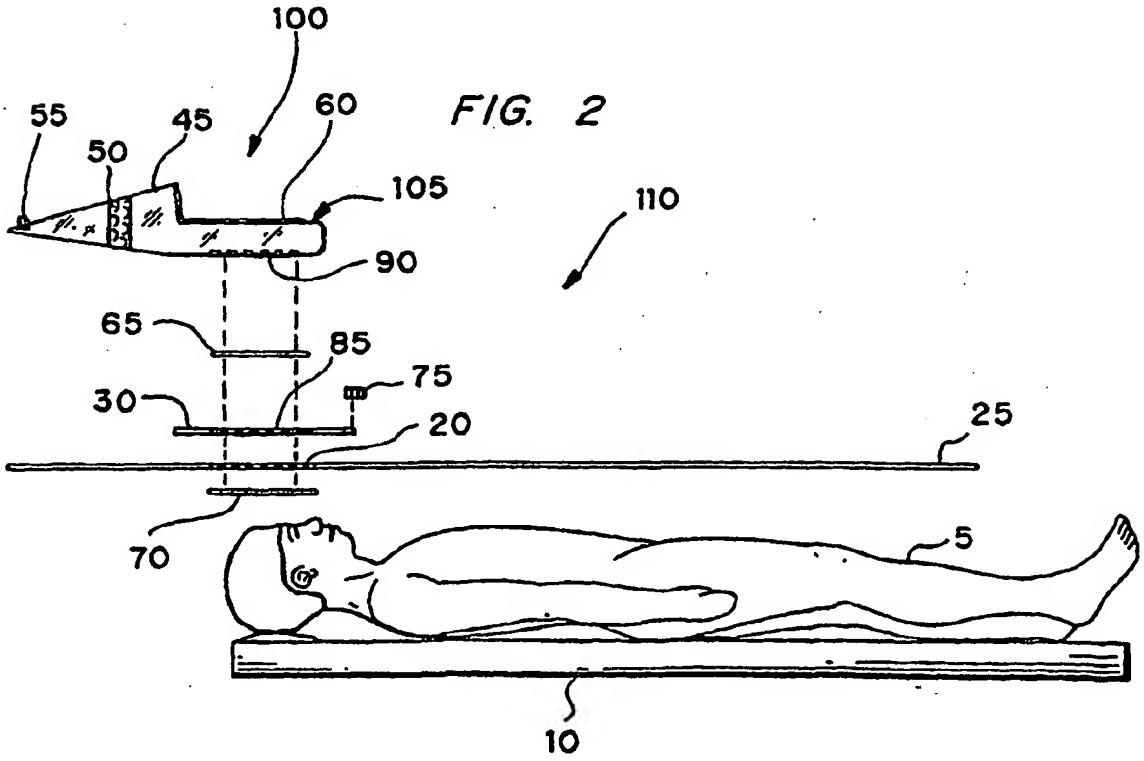

15
30
100
75
75
110
10
25
45
35

FIG. 2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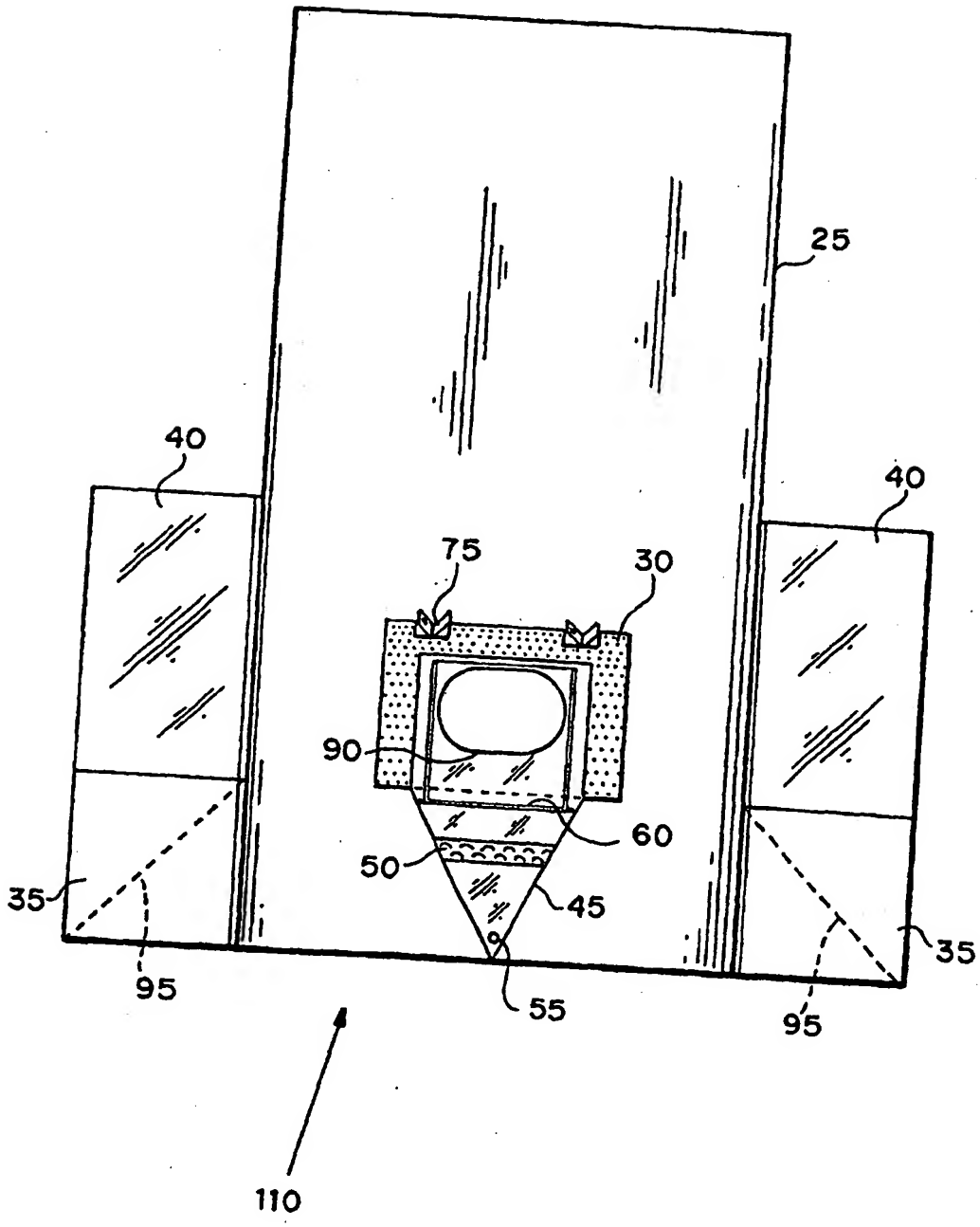
60
50
105
110
90
65
85
75
30
20
25
70
5
10

FIG. 3



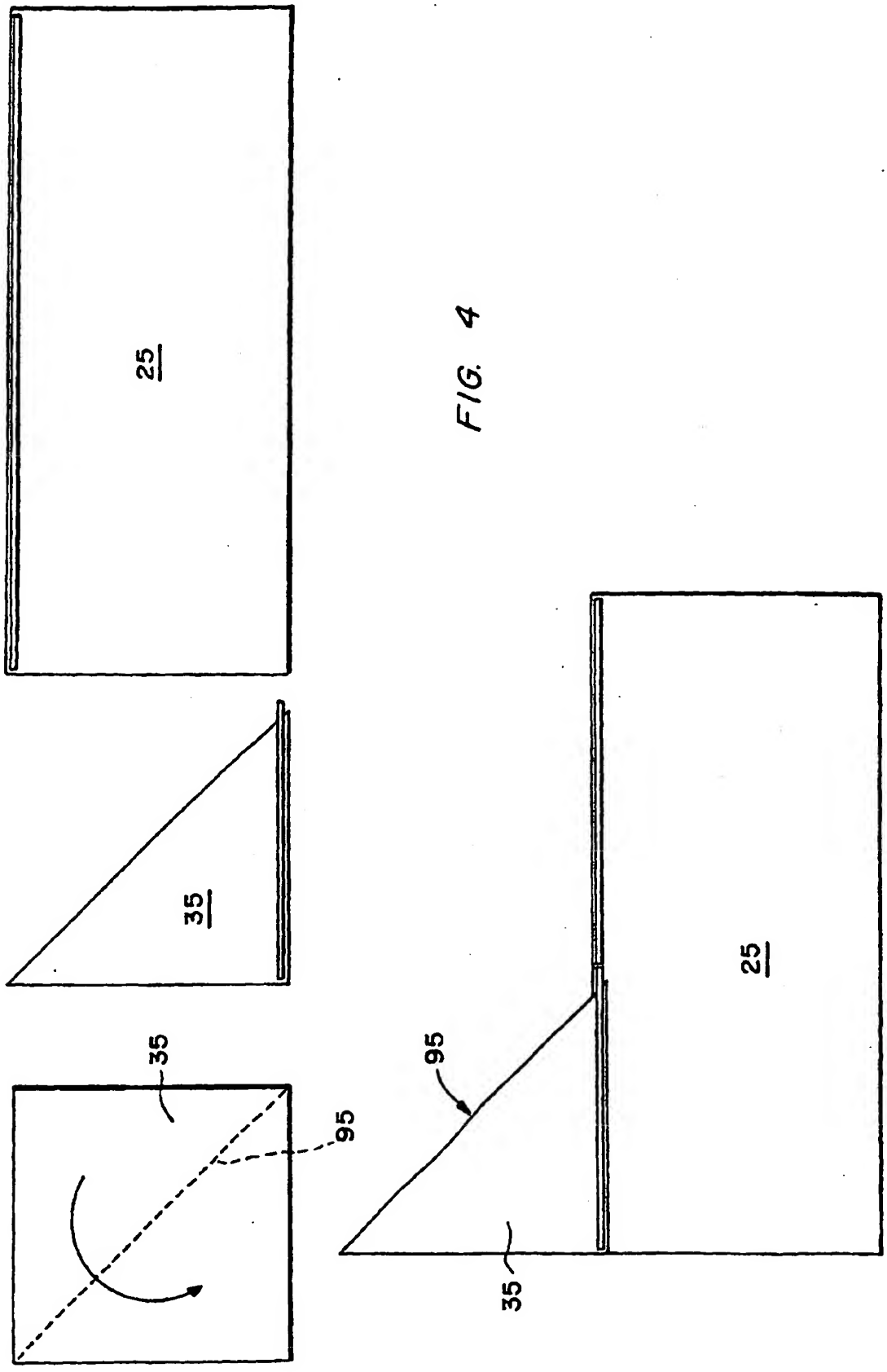


FIG. 4

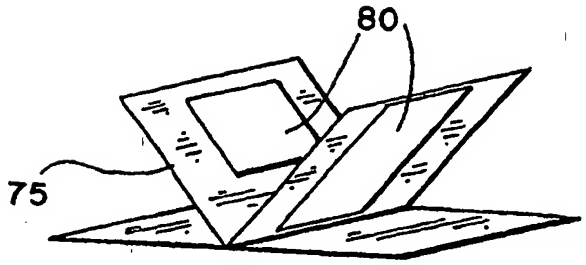
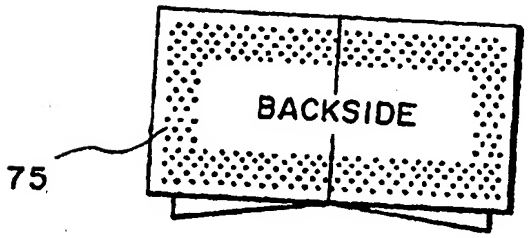


FIG. 5



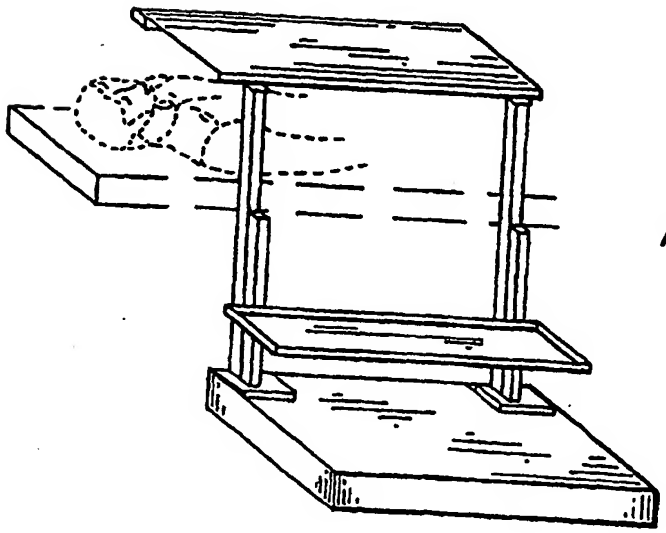


FIG. 6